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10/564,158	04/26/2006	Steffen Sonnenberg	50323	6022

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EXAMINER
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MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3735

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10/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/564,158

Applicant(s)

SONNENBERG ET AL.

Examiner

Charles A. Marmor, II

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3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>20060111</u> . | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Specification***

1. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

2. The specification is objected to for failing to include section headings. Appropriate correction is requested.

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 provides for the method of evaluating the breath of a test subject, but, since the claim does not set forth any active steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 1 recites the limitation "the microbial load" in line 4. There is insufficient antecedent basis for this limitation in the claim.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim

does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c) and 2173.05(d). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation "the volume of the container is variable", and the claim also recites "the container preferably being collapsible."

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c) and 2173.05(d). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the

broad recitation “by exhaling through the mouth”, and the claim also recites “preferably after inhaling through the nose.”

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 6, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/00444 (hereinafter “Mottram”). Mottram teaches a method of evaluating the breath of a test subject. The method includes collecting of a breath sample from the test subject in a container; reducing the microbial load of the breath sample contained in the container, and evaluating the breath sample collected in the container by a tester. The container is filled with breath by the test subject against atmospheric pressure by exhalation. The volume of the container (30, 230) is variable and collapsible. The container possesses an internal surface made of an odourless material. Condensation of moisture in the breath sample will form in the container, and the condensation will inherently reduce the microbial load of the sample as disclosed in the specification of the instant application. The test subject fills the container by exhaling through the mouth, after inhaling through the nose. The breath sample may be anonymised prior to evaluation.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mottram.

Mottram does not expressly close the volume of breath collected in the container.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have filled the container with about 20 ml to 7 l of breath because Applicant has not disclosed that collecting this volume of breath provides an advantage, is used for a particular purpose, or solves a stated problem. Moreover, applicant discloses that this range of volumes encompasses the volume of a single exhalation or a plurality of exhalations. Moreover, it appears that the container and breath collection method of Mottram, or applicant's invention, would perform equally well with any volume consistent with an exhalation volume of a test subject.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Mottram such that the 20 ml to 7 l of breath are collected in the container because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Mottram.

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mottram.

Mottram discloses a temperature adjustment of the breath sample in the container to maintain optimal analysis conditions but does not expressly disclose that the temperature of breath collected in the container is adjusted to 20°C to 40°C prior to evaluation. The specification of the instant application indicates that the normal temperature of breath lies in this

range. Applicant has not disclosed that having adjusting the temperature of the breath sample in the container solves any stated problem or is for any particular purpose. Moreover, it appears that the breath analysis of Mottram, or applicant's invention, would perform equally well with the temperature of the breath sample in the container controlled to a temperature consistent with the temperature of normal breath.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Mottram such that the temperature of the breath sample in the container is adjusted to 20°C to 40°C prior to evaluation because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Mottram.

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sharma et al. in view of Mottram.

Sharma et al. teach a method of evaluating an oral care product. The method includes taking a first breath sample from a test subject, subsequently administering the oral care product to the test subject, taking an additional breath sample from the test subject at a pre-selected time after administering the oral care product, and comparing the first and the additional breath samples by a tester. Sharma et al. teach all of the limitations of the claims except that the breath samples are take from a test subject using a method according to claim 1.

Mottram teaches a method of evaluating the breath of a test subject. The method includes collecting of a breath sample from the test subject in a container; reducing the microbial load of



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the breath sample contained in the container, and evaluating the breath sample collected in the container by a tester.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to have collected breath for evaluation via a method similar to that of Mottram in a method for evaluating an oral care product similar to that of Sharma et al. as a design choice, merely substituting one known means of collecting breath for another that is equally effective in providing breath samples for analysis of an oral care product's effectiveness in combating halitosis.

*Conclusion*

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 6,053,87 to Kharitonov et al. teaches a breath sample reservoir for breath collection and storage. U.S. Patent No. 5,711,306 to Guilluy teaches a device for directly a sample of expired air from a subject.

13. Any inquiry concerning this communication should be directed to Charles A. Marmor, II at telephone number (571) 272-4730.



Charles A. Marmor, II  
SPE  
Art Unit 3735

CAM  
9/28/07